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(54) Title of the Invention: Catheter

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Specification

I. Title of the Invention

Catheter

II. Claims

1. A catheter onto which is mounted a vital organ expander consisting of a shape-memory material, wherein said catheter has a mechanical shape-changing means that mechanically changes the shape of the aforementioned vital organ expander.

III. Detailed Explanation of the Invention

A. Industrial Field of Application

The present invention pertains to a catheter equipped with a vital organ expander used to permanently expand the constricted portion of an organ, such as a blood vessel, trachea or bronchial tube.

B. Prior Art

Conventionally, a catheter known as a PTCA (percutaneous transluminal coronary angioplasty) catheter was inserted in vivo into the constricted portion of the coronary artery, for example, in order to treat cardiac angina or myocardial infarction. However, other possible means for treating the lesions associated with constricted coronary arteries are the use of thrombolytics or mechanical expansion of the constricted portion using a PTCA catheter.

Generally speaking, this type of catheter has a balloon made of plastic or rubber attached to the tip, this balloon is expanded after the catheter is inserted into the constricted portion and after the constricted portion is pressure-expanded due to the expansion of the balloon, a surgical procedure is performed to remove the catheter. The process involved for this method is relatively easy, but is disadvantageous in that the effect is not permanent and the tissues return to their original state with the passage of time and stenosis can easily occur again.

A device has been proposed in U.S. Patent No. 3,868, 956 and Japanese Patent No. S61-6655, for example, for improving this disadvantage in which a cylindrical body made of a shape-memory alloy is implanted into the blood vessel (however, the implanted cylindrical body is subsequently covered by living tissue). In the former example, the expanded state is preliminarily memorized and a cylindrical body made of a shape-memory alloy with a smaller diameter is inserted via a catheter, is heated using an electric method and restored to its original shape in order to expand the blood vessel. In the latter example, a shape-memory alloy plate is processed into a thin diameter by memory-forming it into a cylindrical shape inside the interior diameter of a normal blood vessel, is then inserted into the desired position in the blood vessel via a catheter, is heated using a laser beam or the high-frequency induction heating method and restored to its original shape.

However, in the case of the former device, since the cylindrical body made of the shape-memory alloy is heated by a separate heating element or by an

electrical method in which the electrical resistance of the shape-memory alloy is used to heat the alloy, there is the risk of the occurrence of a short circuit or electric shock and the device is also more complicated. Furthermore, in the case of the latter device, although the laser beam and the high-frequency induction heating method that are used in place of the electric heating method mentioned in the former example are not disclosed, this device is also complicated and expensive.

In addition to the aforementioned application for the blood vessel, the same medical procedure is performed on the trachea and bronchial tube. For example, in the case of lung cancer in which there is pressure on the bronchial tube causing it to become constricted, in order to secure breathing, the trachea is opened up more toward the lungs than the vocal chords and either a catheter is inserted in this location or is inserted into the trachea via the pharynx. In other words, these methods in which a catheter is used to mechanically secure the respiratory tract are commonly used to treat lesions associated with constriction of the trachea or bronchial tube.

However, a disadvantage of the former example is that since the bronchial tube is opened up in order to insert the catheter, once it is inserted, the patient cannot talk, which is not a desirable situation for a patient that is conscious, and the disadvantage of the latter example is that not only can the patient not talk, but there is an extreme sensation of having a foreign object lodged in the throat and the catheter can only be placed for a maximum of one week if the patient is alert.

C. The Process involved in obtaining the Present Invention

The applicant had already proposed a catheter in Patent No. S62-97437 that did not rely on the aforementioned method, that was easy and safe to operate and that realized an expansion method that expanded the constricted portion. This catheter is characterized in that on its tip is provided a blocker (a balloon, for example) that has a function that arbitrarily blocks the blood vessel and/or the flow of body fluid by means of an in vitro operation, to the rear of this blocker and externally fitted into the catheter is a cylindrical body made of a shape-memory alloy that gets restored to a pre-memorized shape at the transition temperature and above, and at the portion where the cylindrical body made of the shape-memory alloy is located is a supply means for supplying heated liquid to the exterior circumference of the catheter. In other words, for this catheter, the desired original shape is pre-memorized, heated liquid is then used to heat the shape-memory alloy cylindrical body that has been processed into a thin diameter, and it is restored to its original shape.

However, after further consideration in relation to the catheter pertaining to the aforementioned patent application, the present inventor found that even though the aforementioned superior effects are achieved, the points described below needed to be improved.

FIG. 16 shows the state in which the catheter described according to aforementioned Patent No. S62-97437 is used and a spiral shaped cylindrical body (hereafter referred to as a coil) functions as the cylindrical body whereby a shape-memory alloy wire wound into a spiral is inserted in the constricted portion of the coronary artery and the aforementioned constricted portion is restored to its

original shape due to the original shape restoration operation of the coil. In this diagram, (A) shows the original shape of the coil before restoration and (B) shows the coil after it has been restored to its original shape.

The heated liquid is fed into coronary artery 20 via the openings in the fine pores formed on the catheter and the temperature of coil 58 made of the shape-memory alloy is raised to the original shape restoration temperature (transition temperature) or above so as to expand the diameter of coil 58 and push and expand constricted portion 21 that is in the periphery of the coil, but if the exterior diameter of coil 58 after it has been restored to its original shape is smaller than the interior diameter of coronary artery 20, the expansion of constricted portion 21 is insufficient. In addition, as shown in FIG. 16 (C), when coil 58 becomes disengaged from the position of constricted portion 21, not only does expansion of the constricted portion become impossible, but once coil 58 has been restored to its original position it becomes impossible to correct the position of coil 58 inside of coronary artery 20 or remove it in a prompt manner. In such cases, the only possible after-treatment is to perform a surgical incision in order to remove the coil.

D. The Purpose of the Invention

The purpose of the present invention is to provide a catheter with improved performance that can sufficiently and reliably expand a vital organ using a vital organ expander and that can also correct the position of the vital organ expander inside the vital organ even after the aforementioned expansion takes place and remove it.

E. Constitution of the Invention

The present invention pertains to a catheter onto which is mounted a vital organ expander made of a shape-memory alloy, wherein said catheter has a mechanical shape-changing means (a balloon, for example) for mechanically changing the shape of the vital organ expander.

F. Working Examples

Next is provided an explanation of the working examples of the present invention.

Working Example 1

FIG. 1 and FIG. 2 show the catheter, and FIG. 1 is a front view, while FIG. 2 is a cross sectional diagram of lines II-II in FIG. 1. However, the vital organ expander (hereafter referred to as the prosthetic material) is shown detached from the catheter unit, and is drawn in a slightly enlarged view in a radial orientation in FIG. 2.

Catheter 1 is equipped with catheter main unit 2 consisting of polyethylene, vinyl chloride, silicone rubber or polyurethane elastomer, on the tip of catheter main unit 2 is provided first balloon 3 made of elastic rubber or plastic, and at the nearer side of first balloon 3 is provided second balloon 4. Lumen 6 and similar lumen 7 for transporting (or draining) air or saline solution to first balloon 3 are each formed by embedding them along the longitudinal direction of catheter main unit 2. In addition, lumen 9, which is for supplying (or draining) warm water to the blood vessel or trachea, is also formed by embedding it along the longitudinal direction of catheter main unit 2, and lumen 9 leads to the outside of

the main unit via opening 5 immediately to the rear of second balloon 4. Lumen 9 is connected to conduit tube 12, which diverges from the main unit, and allows for the supply or drainage of warm water.

Prosthetic material 8 is formed by first forming a thin plate made of shape-memory alloy into a cylinder, memorizing this shape using thermal processing and then re-processing it into a cylinder with a small diameter, and it is then used to enclose second balloon 4 and is fitted to the exterior of said balloon. Air or saline solution is fed (or drained) from conduit tube 10 (that diverges from the main unit) via lumen 6 in order to inflate first balloon 3 (or deflate it to its original shape), and air or saline solution is fed (or drained) from conduit tube 11 (that diverges from the main unit) via lumen 7 in order to inflate second balloon 4 (or deflate it to its original shape). Provided on the center line in the longitudinal direction of catheter main unit 2 are lumen 13 for passing through a guide wire not shown in the diagram and insertion opening 14 that is connected to lumen 13.

As shown in FIG. 12, Catheter 1, which is configured as described above, is inserted from the side at which first balloon 3 is located from femoral artery 22 to coronary artery 20 of living heart 23 (however, the insertion point is shown as a rough sketch in order to make the drawing easier to understand). When this is done, catheter 1 is guided to a predetermined position, but the catheter is effectively guided by means of guide wire 15. Also, the guiding process is monitored by observing catheter 1 and prosthetic material 8 on an X-ray imaging device. Catheter 1 can also be used for expanding constricted portions of other vital organs such as the trachea and other blood vessels in addition to the coronary artery.

FIG. 3 is an enlarged partial cross sectional diagram that shows the process for expanding the constricted portion of the blood vessel or trachea.

First, the guide wire (15 in FIG. 3) is inserted through lumen 13 from the insertion opening 14 shown in FIG. 2, and catheter 1 is inserted into the appropriate location in the blood vessel or trachea (20 in FIG. 3). Then, as shown in FIG. 3 (A), prosthetic material 8 is guided until it reaches constricted portion 21. The position is monitored by means of X-ray illumination.

Next, as shown in (B) of the same diagram, air or saline solution 16 is fed to first balloon 3, said balloon is inflated so as to obstruct the blood vessel or trachea 20 upstream of the constricted portion while at the same time fixing the catheter main unit to the blood vessel or trachea 20. This obstruction is performed for the reasons described below. In other words, the reason is that when the process shown in (C) of the same diagram is used to feed warm water to the blood vessel or to trachea 20 and the warm water flows into trachea 20, it enters the lungs and causes a critical situation. However, in the case of a blood vessel, this obstruction can be omitted.

Next, as shown in (C) of the same diagram, warm water 18 is fed from opening 5 to the blood vessel or trachea 20, the temperature of prosthetic material 8 is raised to the original shape (memorized shape) restoration temperature (transition temperature) or above and is restored to its original shape so as to expand the diameter, which in turn causes constricted portion 21 to expand. For the reason explained above, in this state, the expansion of constricted portion 21

may not be sufficient.

In such a case, as shown in (D) of the same diagram, air or saline solution 17 is supplied to second balloon 4 so as to expand it, which further enlarges the diameter of prosthetic material 8 and sufficiently expands constricted portion 21.

Next, as shown in (E) of the same diagram, in the case of the trachea, warm water 18 is drained and then air or saline solution 16 and 17 are drained and first and second balloons 3 and 4 are both deflated.

Next, as shown in (F) of the same diagram, catheter main unit 2 is extracted and prosthetic material 8 sufficiently expands constricted portion 21 and in this state, prosthetic material 8 is placed and left inside of the blood vessel or trachea 20.

In this manner, the narrowing of the blood vessel or the trachea disappears and the patient's health is restored.

The original shape restoration temperature of prosthetic material 8 should be higher than the body temperature but not high enough to burn, with the most desirable temperature range being between 40~60°C.

As explained above, for the present example, second balloon 4 serves as a mechanical means to aid in expanding the diameter of the blood vessel or trachea due to the restoration of prosthetic material 8 to its original shape.

First balloon 3 is used to block the passageway of a hollow organ by directly obstructing it upstream of the constricted portion, and second balloon 4 is used to enlarge the diameter of prosthetic material 8 and then expand the constricted portion via the enlarged diameter of the prosthetic material. In this manner, by allocating the functions of both the first and second balloons, the burden to each of these balloons is reduced, making it easier to design the catheter. Furthermore, it is undesirable to share the two functions described above with one balloon because the aforementioned blockage of the passageway cannot be secured.

A plurality of through-holes 8a are provided on the periphery wall of prosthetic material 8, and as shown by the state in (F) of FIG. 3, with the passage of time, endothelial tissue is formed from the blood vessel or the trachea until eventually prosthetic material 8 becomes implanted into the blood vessel or trachea 20 due to the presence of through-holes 8a, and the end result is that the expansion of the constricted portion can be hygienically maintained over a long period of time.

When the catheter is inserted through the blood vessel or trachea, it is desirable to devise a means to ensure that prosthetic material 8 does not become disengaged from the position in which second balloon 4 is located. FIG. 4 and 5 are front views of the enlarged portion of the catheter main unit.

For the catheter main unit shown in FIG. 4, small projections 4a, which are point-like projections facing outward along the outer circumference, are formed in a radial pattern at the front and rear tips of second balloon 4. Circular projections 4b are provided on the catheter main unit shown in FIG. 5 in place of the point-like small projections 4a shown in FIG. 4. The prosthetic material externally fitted onto second balloon 4 (not shown in the diagram) is latched to a pair of small projections 4a or circular projections 4b so that it is securely held

around the periphery of second balloon 4 and does not become disengaged.

If a cylindrical net is externally fitted onto first balloon 3 and second balloon 4 (particularly second balloon 4), it is advantageous not only from the aspect of reinforcing these balloons, but also from the aspect of the ability to regulate the inflation of the diameter.

FIG. 6 shows the catheter main unit whereby cylindrical mesh 19 consisting of woven fibers made of Teflon, polyethylene, nylon or polyester is either externally fitted onto (or embedded into) second balloon 4 or is dipped in rubber. In FIG. 6 (A), second balloon 4 is deflated and cylindrical mesh 19 is folded irregularly in order to reduce its diameter. As shown in (B) of the same diagram, when cylindrical mesh 19 is enlarged in diameter and the cylindrical shape is formed, second balloon 4 no longer continues to expand. Therefore, cylindrical mesh 19 not only reinforces second balloon 4, but the diameter of the prosthetic material (not shown in the diagram) fitted onto cylindrical mesh 19 does not only get enlarged to a predetermined diameter, which prevents the constricted portion of the blood vessel or trachea from expanding more than necessary and allows for safe execution of the medical procedure. In addition to the effect as described above, small projections 4a shown in FIG. 4 function to prevent the catheter from digging into cylindrical mesh 19 when it is inserted causing the mesh to become disengaged from second balloon 4. The same effects can be achieved when cylindrical mesh 19 is used for first balloon 3. Therefore, needless to say, either first balloon 3 or second balloon 4 or both balloons may be used. When cylindrical mesh 19 is externally fitted onto first balloon 3, the small projections 4a shown in FIG. 4 can similarly be provided for first balloon 3.

Working Example 2

For prosthetic material 8 in aforementioned Working Example 1, the shape for when the diameter is expanded is memorized, it is then re-processed to a small diameter, the temperature is raised to the transition temperature or above and the diameter is expanded to its original shape. Conversely, in this example, the shape of the diameter of the prosthetic material for when the catheter is inserted or the shape of a similar diameter is memorized and a mechanical force is used to expand the diameter. Catheter main unit 2 that was used in aforementioned Working Example 1 can be used without change as the catheter unit and the same shape of the prosthetic material for when the diameter is small as well as the shape for when the diameter is expanded that were used in the aforementioned Working Example 1 can also be used for Working Example 2.

The expansion of the constricted portion of the hollow organs (the blood vessel or trachea in the case of this example) is executed according to the process shown in FIG. 7.

First, as shown in FIG. 7 (A), as was the case in FIG. 3 (A), prosthetic material 28, which is externally fitted onto second balloon 4 is placed into constricted portion 21 of the blood vessel or trachea 20.

Next, as shown in FIG. 7 (B), air or saline solution 17 is fed into second balloon 4 in order to inflate it, which in turn pushes out and expands prosthetic material 28 so as to enlarge its diameter and expand constricted portion 21.

Next, as shown in FIG. 7 (C), air or saline solution 17 is drained and

second balloon 4 is deflated to its original shape. In this state, prosthetic material 28 plastic-deforms and disengages from catheter main unit 2 with constricted portion 21 in its expanded state.

Next, as shown in FIG. 7 (D), catheter main unit 2 is extracted and prosthetic material 28 is placed inside of the blood vessel or trachea 20 with constricted portion 21 in the expanded state.

Therefore, the constricted portion of the blood vessel or trachea disappears and the patient is restored to health.

If prosthetic material 28 is positioned into constricted portion 21 and is properly expanded, first balloon 3 may be omitted. This is because for the aforementioned process, first balloon 3 is not used. However, as explained below for FIG. 8, in the case that prosthetic material 28 becomes disengaged from constricted portion 21 and the intended expansion of the constricted portion cannot be achieved, first balloon 3 is used in conjunction with prosthetic material 28 and the position of the prosthetic material can either be corrected or it can be removed.

FIG. 8 shows the procedure for the aforementioned operation.

FIG. 8 (A) shows the state in which prosthetic material 28 has become disengaged from constricted portion 21 and placed inside of the blood vessel or trachea 20.

First, as shown in FIG. 8 (B), catheter main unit 2 is inserted through the blood vessel or trachea 20 and second balloon 4 is placed inside of prosthetic material 28.

Next, as shown in FIG. 8 (C), air or saline solution is fed into first balloon 3 in order to inflate it and obstruct the blood vessel or trachea 20.

Next, warm water 18 is fed into the blood vessel or trachea 20 from opening 5 and the temperature of prosthetic material 28 is raised to the transition temperature or above. Then, as shown in (D) of the same diagram, the diameter of prosthetic material 28 is contracted and it is restored to its original shape and then engaged with second balloon 4.

Next, as shown in (E) of the same diagram, air or saline solution 16 is drained and first balloon 3 is deflated to its original shape.

When prosthetic material 28 is removed, catheter main unit 2 is extracted from the blood vessel or trachea 20 in its present state along with prosthetic material 28.

When the position of prosthetic material 28 is corrected, constricted portion 21 is expanded by means of prosthetic material 28 from the state shown in FIG. 8 (E) according to the procedure shown in (A) ~ (D) of FIG. 7 and prosthetic material 28 is placed inside of the blood vessel or trachea 20.

In this manner, the position of the prosthetic material is adjusted to the correct position, the contracted portion of the blood vessel or trachea disappears and the medical procedure is completed.

Needless to say, the examples shown in aforementioned FIG. 4 ~ FIG. 6 can be applied to this Working Example and the same effects can be achieved.

Next is provided an explanation of the items that can be applied to both aforementioned Working Example 1 and Working Example 2.

Prosthetic materials 8 and 28 may be covered with a flexible material that has superior biocompatibility. Woven or knitted polyester fabric, a porous polytetrafluoroethylene membrane or a silicone, polyurethane or polyacrylic acid ester (or meta) membrane can be used as the covering material. Layers of thin cloth made of any of the aforementioned membrane materials can also be used. In addition, an antithrombogenic agent such as Peparin* can be used for the covering material. These covering materials function to promote the implantation of the prosthetic material due to the formation of endothelial tissue, as described above, and additionally help to prevent thrombi.

FIG. 9 is an enlarged partial cross sectional view of a prosthetic material that has been covered with the aforementioned type of material. On the surface of prosthetic material 8 (28) consisting of a shape-memory material, is applied a layer of the aforementioned covering material 8c (28c), which includes the inner circumference of through-holes 8a (28a).

In addition, as shown in the enlarged view of FIG. 10, by forming indents 8d (28d) on the surface of prosthetic material 8 (28) consisting of the shape-memory material, or as shown in the enlarged view of FIG. 11, by transplanting fiber hairs 8e (28e) consisting of the aforementioned material in addition to or in place of covering material 8c (28c) shown in FIG. 9, the placement of the prosthetic material to the blood vessel or trachea becomes more secure.

In addition to the shape of the aforementioned prosthetic material 8 and 28, the following shapes may also be used.

Prosthetic material 38A shown in FIG. 13A is a plate-like shape-memory material in which the plate has been formed into a cylindrical shape onto which several slits 38Aa are provided, prosthetic material 38B shown in FIG. 13B is similarly shaped into a rib-like cylinder onto which are formed several slits 38Ba. Prosthetic material 38C shown in FIG. 13C is a plate consisting of the shape-memory material that has been formed into a conical trapezoid that is used to expand the portion of the diameter of hollow organs such as the blood vessel or trachea that changes. Figures 13A, 13B and 13C all show the state in which the diameter has been enlarged. Prosthetic material 38D shown in FIG. 13D is a plate consisting of a shape-memory material that has been formed into a cylindrical shape that is not provided with through-holes, and prosthetic material 38E shown in FIG. 13E is a tube consisting of shape-memory material that has been folded in the radial direction so as to process it into a small diameter. Both prosthetic materials are shown in the deflated state, and when their diameters are enlarged, they form a cylindrical shape with a diameter that is larger than that shown in the diagram. Needless to say, prosthetic material 38C shown in FIG. 13C, prosthetic material 38D shown in FIG. 13D, prosthetic material 38E shown in FIG. 13E can all be provided with the through-holes or slits, such as aforementioned through-holes 8a, slits 38Aa shown in FIG. 13A, or slits 38Ba shown in FIG. 13B.

Although the examples shown in Figures 13A ~ 13E are prosthetic material formed from a plate or tube consisting of shape-memory material, the raw material can be either a strip or wire material.

*[Translator's comment: although the document says, "*Peparin*", the translator believes that this is a misspelling for *Heparin*.]

FIG. 13F shows prosthetic material 38F consisting of a strip of shape-memory material that is wound in a spiral form, FIG. 13G shows prosthetic material 38G consisting of a wire of shape-memory material that is wound in a spiral form. FIG. 14A is a cross sectional view of prosthetic material 38F. The cross section of the wire material for prosthetic material 38G can be circular such as that shown in FIG. 14C, or oval such as that shown in FIG. 14E. And, in addition, besides forming these materials by means of adhesion, they can also be formed at intervals into a spiral shape, such as that shown in Figures 14B, 14D and 14F. It is advantageous to form the material at intervals as described above because this promotes the implantation of the prosthetic material into the hollow organ, such as the blood vessel or trachea, due to the formation of the endothelial tissue. Prosthetic material 38H shown in FIG. 13H is a coil made of shape-memory material that has been further formed into a spiral shape. Prosthetic materials 38I in FIG. 13I and 38J in FIG. 13J are wire material made of shape-memory material that has been shaped into a spiral with a diameter that is partially different and both of these prosthetic materials are used to expand the portion of the diameter of the blood vessel or trachea that changes. Prosthetic materials 38F ~ 38J in Figures 13F ~ 13J are all shown in the expanded state.

The same type of surface can be applied to the prosthetic materials in Figures 13A ~ 13J that was described above.

In addition to shape-memory alloy, shape-memory resin can also be used for the prosthetic material. Shape-memory resin is a resin that has the same original shape restoration capability as the aforementioned shape-memory alloy, and one example of a shape-memory resin is norbornene resin (for example of the product name of *Norsrex*). Other examples are trans-1, 4-polyisoprene, styrene-butadiene copolymer, or polyurethane. Shape-memory resin can be described as follows. It is a resin in which the shape is memorized at room temperature for when thermal formation (primary formation) takes place, its temperature is higher than glass transition temperature (Tg) but lower than the primary formation temperature, it is secondarily formed into another shape and then this is restored to room temperature. When this is at glass transition temperature or above and then re-heated again to a temperature that is lower than the primary formation temperature, it is restored to the shape that was memorized when primary formation took place.

Prosthetic materials 38A ~ 38J (particularly 38A ~ 38F) shown in Figures 13A ~ 13J (particularly 13A ~ 13F) can be manufactured using shape-memory resin at a temperature that is at body temperature or above (preferably at a range of 40~60°C) and that is at the glass transition temperature that does not cause burning. In addition, prosthetic material 48A, which is the cylindrical body shown in FIG. 15A, and prosthetic material 48B, which is the reticular cylindrical body shown in FIG. 15B can also be manufactured. The same is true for prosthetic material made of shape-memory alloy.

An explanation has been provided of the working examples for the present invention but various modifications can be made to the aforementioned examples based on the technological idea of the present invention. For example, a sheath

(cylindrical body 59 in FIG. 16) can be externally fitted into the catheter unit in place of lumen 9 for catheter main unit 2, and warm water can be fed to the prosthetic material from between this sheath and the catheter main unit. Warm water, infusion fluid, or contrast agent can be used for the fluid that is fed to the first balloon and the second balloon instead of air or saline solution. Contrast agent can be injected into lumen 13 (refer to FIG. 2) instead of the guide wire. An oval or some other appropriate shape can be used instead of the circular shape that is formed around the external circumference of the first and second balloons and the prosthetic material, or it can also be straight in the longitudinal direction, or it can be a curve, based on the intended application. Although a shape that does not return to its original shape after transition (irreversible transition), such as was described above, is the most desirable for the shape of the shape-memory alloy or resin, various kinds of transition shapes may be selected. In addition, depending upon the intended application, the transition may also be reversible (contracts when cooled). Moreover, the position in which the shape-memory material is placed and its pattern is not limited to those described above. The expansion of the prosthetic material may be carried out with the inflation of the second balloon or it may be performed when the shape of the shape-memory alloy or resin for which the transition is reversible is restored to its original shape or may be carried out according to any other mechanical method for enlarging the diameter of the prosthetic material. Furthermore, the catheter (in other words the prosthesis) may be inserted into the portion of these organs which has become thinner and can be easily torn, such as an arteriovenous aneurysm, in addition to the constricted portion of hollow organs such as the blood vessel, trachea or bronchial tube, as described above.

G. Effects of the Invention

The catheter pertaining to the present invention has a mechanical shape-changing means for mechanically changing the shape of a vital organ expander consisting of a shape-memory material, whereby the shape of the vital organ expander is mechanically changed in the direction that restores it to the memorized shape and in the reverse direction, and these changes in shape can be done sufficiently and reliably using a mechanical method. As a result, the performance of the vital organ expander can be improved.

IV. Brief Explanation of the Drawings

Figures 1~15 show working examples of the present invention.

FIG. 1 is a front view of the catheter that shows the vital organ expander (prosthetic material) detached from the catheter main unit, and FIG. 2 is a cross sectional view of line II-II shown in FIG. 1.

FIG. 3 (A), (B), (C), (D), (E) and (F) are all enlarged partial cross sectional views of the procedure for expanding the constricted portion of a hollow organ, such as a blood vessel or trachea.

FIG. 4 and FIG. 5 are both enlarged partial front views of catheters pertaining to other examples.

FIG. 6 shows a catheter unit that pertains to yet another example and (A) in the diagram is an enlarged partial front view of before the diameter is expanded

and (B) in the diagram is an enlarged partial view of when the diameter is expanded.

FIG. 7 (A), (B), (C) and (D) are all enlarged partial cross sectional views (partially perspective views) of the procedure for expanding the constricted portion of the blood vessel or trachea that pertain to other examples.

FIG. 8 (A), (B), (C), (D) and (E) are all enlarged partial cross sectional views (partially perspective views) of the procedure that allows for deflating the diameter of, correcting the position of, and removing the prosthetic material that is expanded and placed inside of the blood vessel or trachea.

FIG. 9 is an enlarged partial cross sectional view of the prosthetic material.

FIG. 10 and FIG. 11 are enlarged partial front views of the prosthetic material that pertain to other examples.

FIG. 12 is schematic view of when the catheter is inserted into the coronary artery.

FIG. 13(A), FIG. 13(B), FIG. 13(C), FIG. 13(D), FIG. 13(E), FIG. 13(F), FIG. 13(G), FIG. 13(H), FIG. 13(I) and FIG. 13(J) are all enlarged perspective views of the prosthetic material pertaining to other examples.

FIG. 14 (A), FIG. 14(B), FIG. 14 (C), FIG. 14 (D), FIG. 14 (E) and FIG. 14 (F) are all enlarged partial cross sectional views of spiral prosthetic material.

FIG. 15 (A) and FIG. 15 (B) are enlarged perspective views of the prosthetic material that pertain to other examples.

FIG. 16 shows the implantation state of the shape-memory alloy coil inserted inside the blood vessel with a conventional catheter. (A) is an enlarged cross sectional view of before the implantation takes place and (B) and (C) are enlarged cross sectional views of after the implantation takes place.

The reference symbols used in the figures are as follows.

1	… … …	Catheter
2	… … …	Catheter main unit
3	… … …	First balloon
4	… … …	Second balloon
5	… … …	Opening for infusing warm water
6, 7, 9 13	… … …	Lumens
8, 28, 38A, 38B, 38C, 38D, 38E, 38F, 38G, 38H, 38I, 38J, 48A, 48B	… … …	Vital organ expanders (prosthetic material)
15	… … …	Guide wire
16	… … …	Air
17	… … …	Air or saline solution
18	… … …	Warm water
19	… … …	Mesh
20	… … …	Blood vessel or trachea
21	… … …	Constricted portion of the blood vessel or trachea

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第１３Ａ図、第１３Ｂ図、第１３Ｃ図、第１３Ｄ図、第１３Ｅ図、第１３Ｆ図、第１３Ｇ図、第１３Ｈ図、第１３Ｉ図及び第１３Ｊ図は夫々他の例による補綴材の拡大斜視図、

第１４Ａ図、第１４Ｂ図、第１４Ｃ図、第１４Ｄ図、第１４Ｅ図及び第１４Ｆ図は夫々螺旋状補綴材の拡大部分断面図、

第１５Ａ図及び第１５Ｂ図は更に他の例による補綴材の拡大斜視図

である。

第１６図は従来のカテーテルを使用しての血管内での形状記憶合金製コイルの転移状況を示し、同図（Ａ）は転移前の拡大断面図、同図（Ｂ）及び（Ｃ）は転移後の拡大断面図である。

なお、図面に示された符号において、

１……カテーテル

２……カテーテル本体

３……第一のバルーン

４……第二のバルーン

５……温水注入用開口

６、７、９、１３……ルーメン

８、２８、３８Ａ、３８Ｂ、３８Ｃ、３８Ｄ、３８Ｅ、３８Ｆ、３８Ｇ、３８Ｈ、３８Ｉ、３８Ｊ、４８Ａ、

４８Ｂ……生体器官拡張器（補綴材）

１５……ガイドワイヤ

１６……空気

１７……空気又は生理食塩水

１８……温水

１９……メッシュ

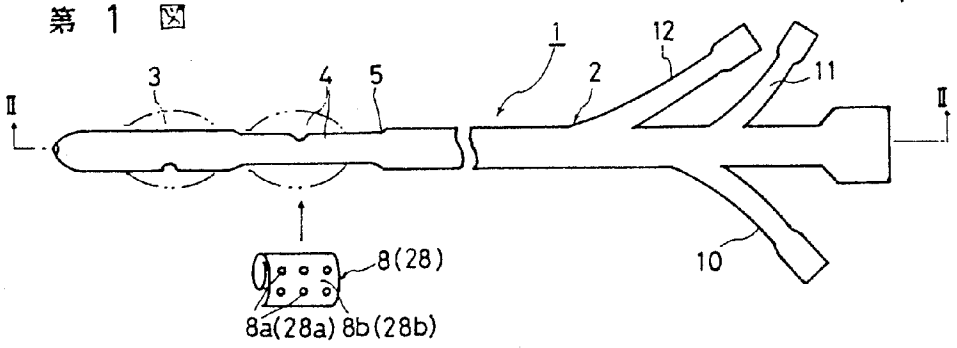
２０……血管又は気管

２１……血管又は気管の狭窄部

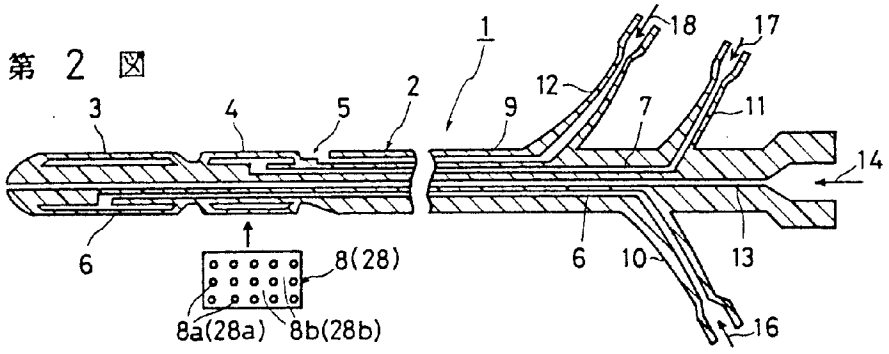
である。

代理人　　弁理士　　逢坂　宏

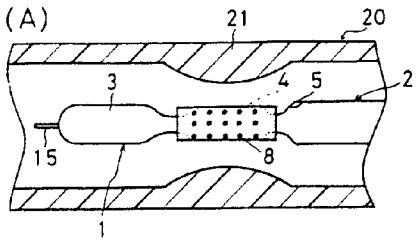
第１図

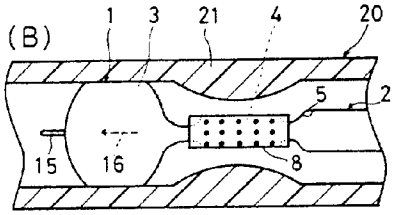


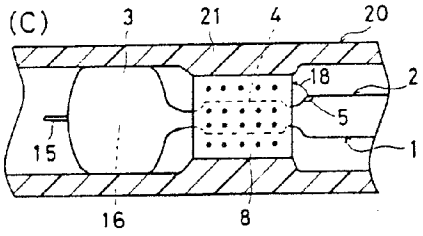
第２図



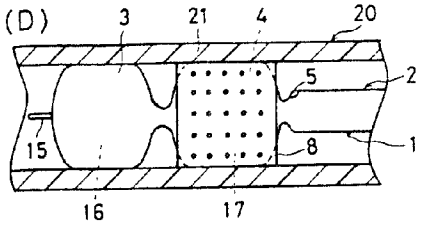
第 3 図

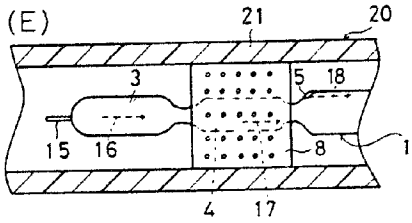


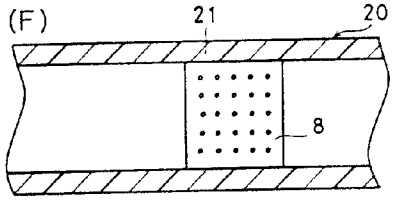


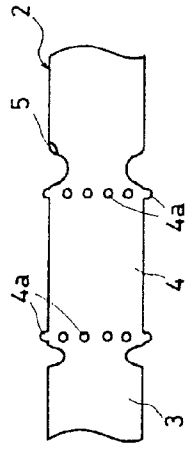


第 3 図

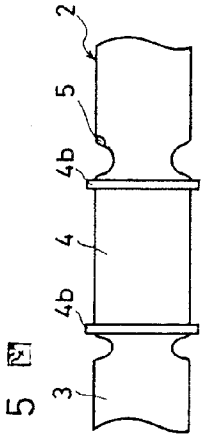




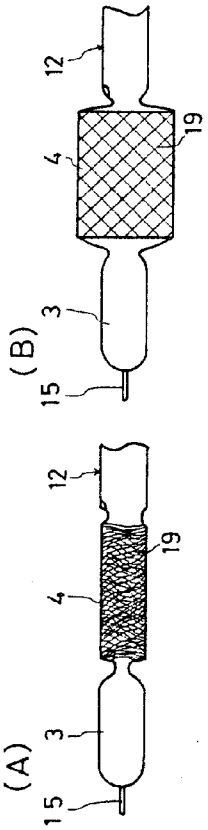




第 4 図

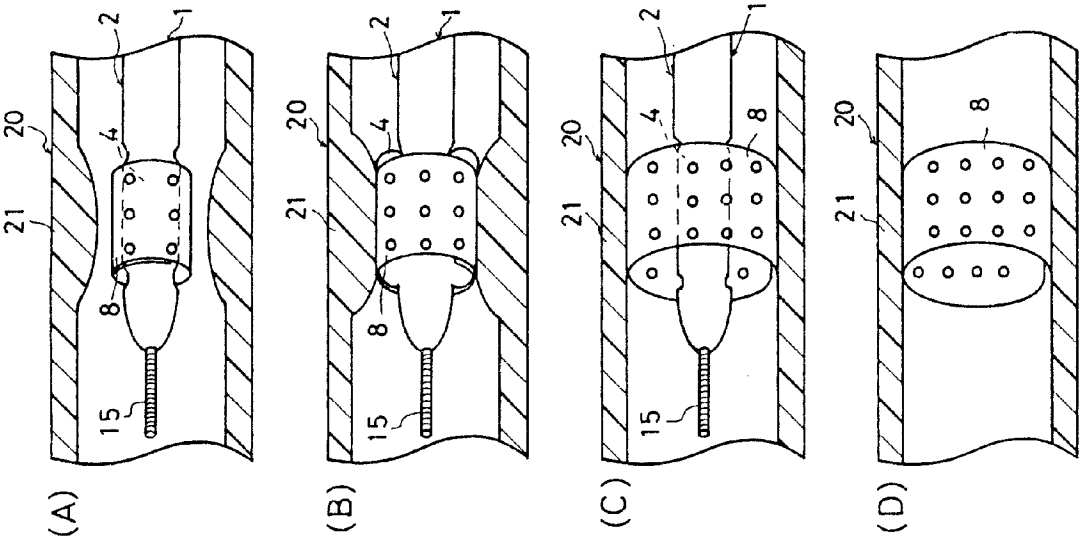


第 5 図

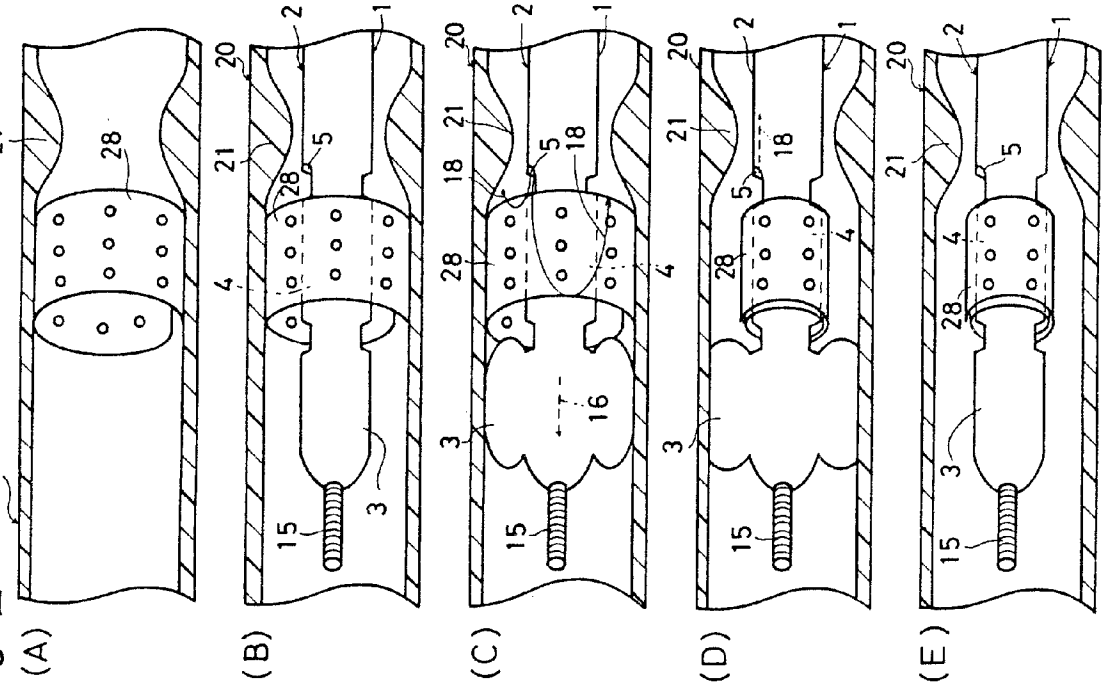


第 6 図

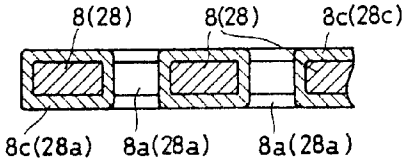
第7図



第8図



第 9 図



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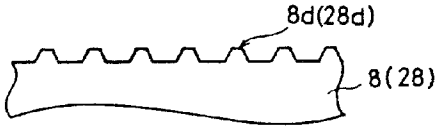
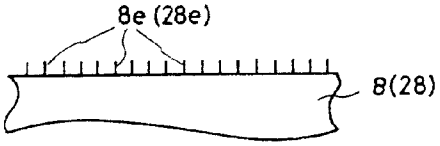
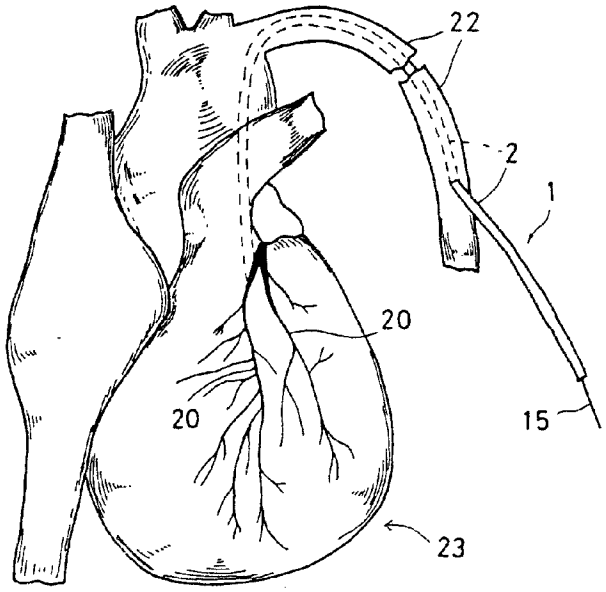


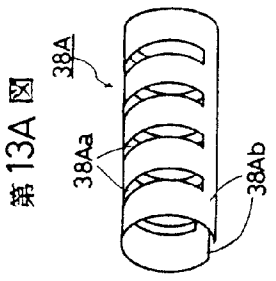
第 11 図



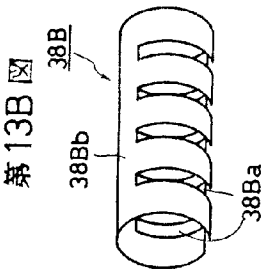
第 12 図



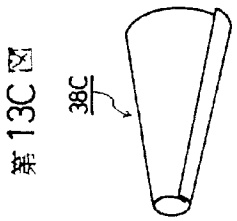
第 13A 図



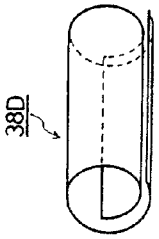
第 13B 図



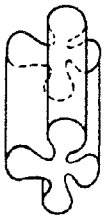
第 13C 図



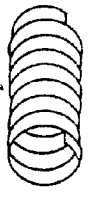
第 13D 図



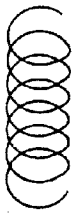
第 13E 図



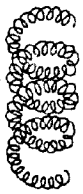
第 13F 図



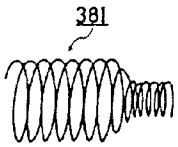
第 13G 図



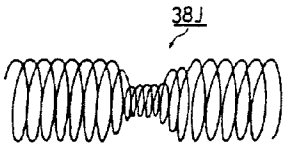
第 13H 図



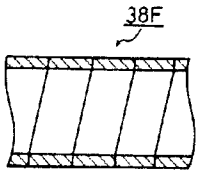
第13I図



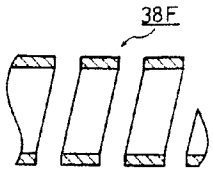
第13J図



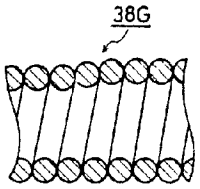
第14A図



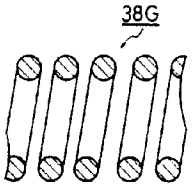
第14B図



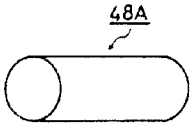
第14C図



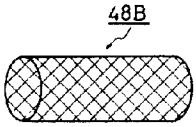
第14D図



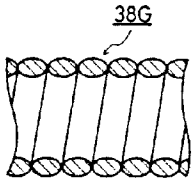
第15A図



第15B図



第14E図



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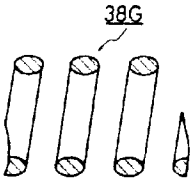
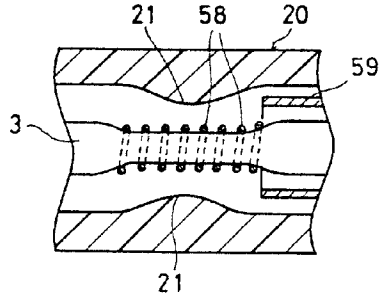


第16図

(A)



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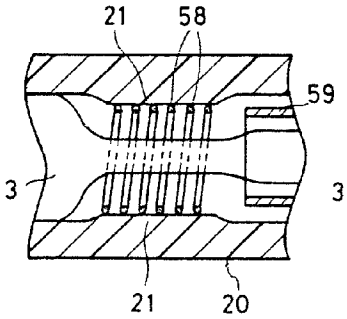

(C)